Brent O. Hatch (5715)
Hatch@Hatchpc.com
HATCH LAW GROUP, P.C.
22 East 100 South, Suite 400
Salt Lake City, Utah 84111
Telephone: (801) 869-1919

Attorneys for Predictive Biotech, Inc.

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

PREDICTIVE BIOTECH, INC., a Utah corporation, Plaintiff, v. AUXOCELL LABORATORIES, INC., a Delaware corporation, Defendant.	**COMPLAINT** **(Jury Trial Demanded)** Case: _____ Judge: _____

Plaintiff Predictive Biotech, Inc. ("PBIO"), by its undersigned counsel, alleges, on knowledge as to its own conduct and otherwise on information and belief, as follows:

INTRODUCTION

1. This case involves the manufacture and sale of defective Auxocell Solid Tissue Processing Systems ("AC:Px") by Defendant Auxocell Laboratories, Inc. ("Auxocell") and the resulting damages to PBIO of approximately $100 million. Auxocell understood the exact need and exact tissues PBIO would be using the AC:Px for and represented that the product would meet

those needs. Auxocell understood that the AC:Px would be integral to the most critical aspects of PBIO's business in processing tissues and agreed to provide the units.

PARTIES

2. PBIO is a Utah corporation with its principal place of business in Salt Lake County, Utah. PBIO conducts business in this judicial district.

3. Auxocell is a Delaware corporation, with its principal place of business in Cambridge, Massachusetts. Auxocell contracted and partially performed its transactions with PBIO in this judicial district.

JURISDICTION AND VENUE

4. This case involves citizens of different states, and the district courts of the United States have original jurisdiction of all civil actions between citizens of different states where the matter in controversy exceeds, as it does here, the sum or value of $75,000, exclusive of interest and costs. 28 U.S.C. § 1332(a).

5. Because the claims and the matter in controversy exceed the sum or value of $75,000, exclusive of interest and costs, this Court has original jurisdiction of the action.

6. The Court has personal jurisdiction over Auxocell because it has conducted business in this judicial district.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391, as a substantial part of the actions giving rise to the claims herein occurred in this District.

GENERAL ALLEGATIONS

8. Established in 2015, PBIO is the pioneer in human cell and tissue products for use in regenerative medicine. PBIO's success is the result of its history of innovation, customer focus, and exceptional quality products.

9. Auxocell markets itself as a leading solid tissue processing equipment manufacturing company. Because of Auxocell's represented experience and expertise in solid tissue processing equipment, PBIO was interested in purchasing Auxocell's AC:Px Systems to process specific tissues.

10. As by Auxocell's CEO, the AC:Px was intended to reduce solid tissue into small pieces and to release cytokines, growth factors and/or cells if cells are already present in the solid tissue being processed.

11. Part of the AC:Px involves a cutting surface, which is comprised of a blade, a screen, a second blade, and then a second screen with a smaller diameter that are designed to cut like scissors to produce the desired minced tissue.

12. Each AC:Px unit is supplied sterile, for a single use only. After each use, the AC:Px must be replaced. Accordingly, PBIO must buy a significant number of AC:Px units to meet its needs.

13. PBIO explained to Auxocell that PBIO would use the AC:Px to process umbilical cord tissue, amnion/chorion tissue, placenta tissue, and adipose tissue, which required sterile conditions and uncontaminated results. Auxocell affirmed that the AC:Px would be able to process those types of tissues, in the manner needed by PBIO.

14. As part of its communications with Auxocell, PBIO stated that it would make every effort to implement and utilize the AC:Px as its primary processing technology. This entailed PBIO changing its method of processing umbilical cord tissue to a mode compatible with the AC:Px.

15. After meeting with Auxocell and explaining in detail PBIO's needs, Auxocell signed a non-binding Technology License and Option to Purchase Term Sheet ("Term Sheet") dated July 14, 2017 and sent that Term Sheet to PBIO.

16. While the Term Sheet was non-binding and PBIO did not sign it, the Term Sheet laid out the fundamentals of PBIO's and Auxocell's agreement.

17. During their discussions, the parties clearly identified the use of the AC:Px, unit pricing, and desire of Auxocell for PBIO to utilize the AC:Px as its primary processing technology.

18. Consistent with that understanding, PBIO began to order the AC:Px units from Auxocell in July 2017.

19. From July, 2017 to approximately February 2019, Auxocell's AC:Px units purchased by PBIO functioned properly and as represented, and PBIO expanded its business around the use of the AC:Px.

20. On February 28, 2019, PBIO identified a problem with the AC:Px that caused the resulting tissue samples to contain visible amounts of metal particulates after being processed with the device, rendering the subsequent processed tissue contaminated, useless, and therefore worthless.

21. PBIO reported the issue to Auxocell.

22. An investigation was instituted to address the issue and develop a Corrective and Preventative Action, CAPA-20190404-01.

23. The CAPA-20190404-01 was a "for-cause" audit initiated in response to the complaint from PBIO about the presence of metal particulates in the tissue when processed with the AC:Px.

24. Auxocell issued a "Batch Release Plan" finding that the metal contaminants in the samples "corresponded to a change in the supplier of the blades and screens" incorporated in the AC:Px, as well as Auxocell's lack of specifications provided to supplier of blades and screens for the AC:Px.

25. On May 13, 2019, and as a result of the audit, Auxocell proposed corrective action including, but not limited to, the need to "determine additional blade and screen specifications" that would prevent the metal particulates from entering the final product.

26. "The expected completion timeframe for the [proposed corrective] actions [was] September – November, 2019."

27. In August 2019, the AC:Px units failed internal PBIO tests.

28. On October 1, 2019, PBIO and Auxocell started to again investigate why metal particulates were left in the tissue samples, rendering them contaminated, useless, and therefore worthless.

29. PBIO CAPA-20190404-01 investigation was still open as of October 2019, because Auxocell had not provided a final resolution to the original findings. Auxocell stated that it was continuing to work with its suppliers to determine causes of the AC:Px malfunction. Results of the new investigation were due December 9, 2019.

30. On October 16, 2019, PBIO requested a timeline for when Auxocell would be able to produce a non-defective product. PBIO explained that "[t]he loss of revenue because of lost processed inventory per week [was] extensive[.]"

31. Auxocell confirmed that the issue was due to the non-conforming blades from its supplier and promised to correct the issue with new blades, improved inspection measures, and investigating additional methods to prevent the debris from contaminating the tissue.

32. To date, Auxocell has still not provided PBIO with an adequate response to the open CAPA-20190404-01, detailing the root cause analysis and corrective action plan for resolving the issues with the AC:Px system.

33. PBIO last received a shipment of the AC:Px from Auxocell on November 11, 2019. It was determined by both parties that the AC:Px product that was received in this shipment was defective and PBIO was unable to process tissue utilizing these units.

34. Auxocell has failed to resolve the issues with the AC:Px, causing ongoing damages to PBIO.

35. As a result of Auxocell's deficient products and inadequate resolution of the problems with the AC:Px, PBIO has incurred extensive damage to its revenues, harm to its ability to maintain and/or grow its business, and other losses. Those damages include, but are not limited to, wasted umbilical cord tissue, lost potential inventory, product substitution costs, supplies, particulate testing, and reputational damage, in an amount to be determined at trial but is believed to be in excess of $100 million.

36. Auxocell has given no reliable timetable by which it would be able to provide PBIO with non-defective AC:Px systems.

FIRST CLAIM FOR RELIEF
(Breach of Contract or the alternative Breach of Implied Contract)

37. PBIO hereby incorporates by reference each and every allegation contained in the proceeding paragraphs as if fully set forth herein.

38. PBIO and Auxocell entered into an agreement, whether express or implied. The terms of that agreement are at least the following:

a. Auxocell would provide AC:Px operational units in sufficient numbers needed by PBIO to perform its tissue processing.

b. The AC:Px units would perform the tissue processing as described by PBIO to Auxocell.

c. PBIO was to, and did, make every effort to implement and utilize the AC:Px technology as its primary processing technology.

d. PBIO would pay for the units.

39. In the alternative, such agreement was established by the parties' conduct and PBIO's payments to Auxocell in exchange for AC:Px units.

40. Auxocell was aware of this exchange of consideration and agreed to perform under these terms, expressly, or in the alternative, by its conduct.

41. Auxocell provided AC:Px units to PBIO, and PBIO paid for the units.

42. PBIO performed all of its obligations under the contract.

43. Auxocell has not performed its required obligations under the contract including, but not limited to, supplying functional, non-defective AC:Px units.

44. As a result of Auxocell's breaches, PBIO has been damaged and will continue to be damaged in an amount to be determined at trial, but in no event less than the value of the wasted umbilical cords, lost potential inventory, lost profits, product substitution costs, supplies, particulate testing, future expenses to replace damaged property, and all other damages incurred as a result of Auxocell's breach, including the attorney fees and costs associated with this litigation. PBIO has also suffered damage to its reputation, and its relationships with customers and potential customers.

SECOND CLAIM FOR RELIEF
(Strict Liability – Product Liability Design Defect)

45. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

46. On information and belief, the AC:Px design was defective because Auxocell's specifications for the blades and screens lacked the required specificity to create a properly functioning product.

47. On information and belief, the defect existed at the time the AC:Px was sold to PBIO.

48. The inadequate specifications for the blades and screens made the AC:Px unreasonably dangerous because it caused metal particulates to be left in the tissues being processed causing property damage.

49. The audit of Auxocell's AC:Px found that Auxocell needed to improve the specifications of its AC:Px blades and screens provided to its suppliers in order to address the defective blades and screens in the AC:Px that resulted in metal particulates contaminating the tissue samples.

50. As a direct and proximate result of Auxocell's malfunctioning product, PBIO has

been unable to process the tissue samples, and could not sell or use the samples that had already been processed using the defective equipment from Auxocell.

51. As a direct and proximate result of Auxocell's product and the halt in production, PBIO has incurred and continues to incur damages including, but not limited to, the value of the wasted umbilical cords, lost potential inventory, lost profits, product substitution costs, supplies, particulate testing, future expenses to replace damaged property, and all other damages incurred as a result of Auxocell's breach, including the attorney fees and costs associated with this litigation. PBIO has also suffered damage to its reputation, and its relationships with customers and potential customers.

THIRD CLAIM FOR RELIEF
(Strict Liability – Product Liability Manufacturing Defect)

52. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

53. On information and belief, Auxocell claimed that it had changed the supplier of the AC:Px blades and screens at some point prior to April 2019. On information and belief, at some point after PBIO began using AC:Px units containing the blades and screens from a second supplier, the product became unreasonably dangerous to property as metal particulates entered the tissues being processed causing the end product to be both useless and worthless.

54. On information and belief, the defect existed at the time the AC:Px was sold to PBIO.

55. PBIO reported the issue to Auxocell, resulting in an audit of the defective product.

56. The auditcr found that the change in blade and screen manufacturers corresponded to the faulty blades and screens.

57. Additionally, the audit found that the blades from the new supplier differed in

geometry, hardness, and finish from the original supplier. This difference caused the metal particulates to be left in the processed tissue.

58. As a direct and proximate result of Auxocell's defective product and the resulting halt in production, PBIO has incurred and continues to incur damages including, but not limited to, the value of the wasted umbilical cords, lost potential inventory, lost profits, product substitution costs, supplies, particulate testing, future expenses to replace damaged property, and all other damages incurred as a result of Auxocell's breach, including the attorney fees and costs associated with this litigation. PBIO has also suffered damage to its reputation, and its relationships with customers and potential customers.

FOURTH CLAIM FOR RELIEF

(Breach of Implied Warranty of Merchantability – Utah Code Ann. § 70A-2-314)

59. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

60. "[A] warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to the goods of that kind." Utah Code Ann. § 70A-2-314(1).

61. Auxocell markets itself as a leading solid tissue processing equipment manufacturing company.

62. Auxocell marketed and sold the AC:Px as a device that could reduce solid tissue into small pieces and to release cytokines, growth factors and/or cells if cells were already present in the solid tissue being processed in a sterile and uncontaminated manner.

63. PBIO received and relied on Auxocell's representations regarding the quality and uses of the AC:Px, and purchased the AC:Px for uses consistent with those for which Auxocell

marketed the product. When PBIO used the AC:Px as intended by Auxocell, the unit left metal particulates in the processed tissue, rendering the tissue samples both useless and worthless.

64. The metal particulates in the sample resulted from the failure of the AC:Px to have the expected quality, and was the direct and proximate cause of PBIO's harm.

65. It was reasonably foreseeable to Auxocell that PBIO would use the AC:Px in the manner it did.

66. As a direct and proximate result of Auxocell's product and the halt in production, PBIO has incurred and continues to incur damages including, but not limited to, the value of the wasted umbilical cords, lost potential inventory, lost profits, product substitution costs, supplies, particulate testing, future expenses to replace damaged property, and all other damages incurred as a result of Auxocell's breach, including the attorney fees and costs associated with this litigation. PBIO has also suffered damage to its reputation, and its relationships with customers and potential customers.

FIFTH CLAIM FOR RELIEF

(Breach of Implied Warranty of Fitness for a Particular Purpose – Utah Code Ann. § 70A-2-315)

67. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

68. Auxocell had reason to know that PBIO was purchasing the AC:Px for the particular purpose of processing certain human tissues in a sterile and uncontaminated manner because of the numerous conversations between the two parties regarding PBIO's needs. *See* Utah Code Ann. § 70A-2-315.

69. PBIO relied on Auxocell's skill and judgment in the field of tissue processing

machines, and Auxocell knew that PBIO was relying on Auxocell's expertise to furnish a suitable product. *See Id.*

70. Auxocell furnished the AC:Px, which left metal particulates in the processed tissues rendering the resulting product both useless and worthless making it unfit for the particular purpose for which PBIO bought it.

71. The contaminated product resulted from PBIO's use of the AC:Px in the particular manner and for the precise purpose for which Auxocell supplied the units.

72. As a direct and proximate result of Auxocell's product and the halt in production, PBIO has incurred and continues to incur damages including, but not limited to, the value of the wasted umbilical cords, lost potential inventory, lost profits, product substitution costs, supplies, particulate testing, future expenses to replace damaged property, and all other damages incurred as a result of Auxocell's breach, including the attorney fees and costs associated with this litigation. PBIO has also suffered damage to its reputation, and its relationships with customers and potential customers.

SIXTH CLAIM FOR RELIEF
(Negligent Misrepresentation)

73. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

74. Shortly before the parties entered into their agreement, Auxocell represented to PBIO that it could and would provide equipment that would be suitable for use in a process that required sterile conditions and uncontaminated results.

75. These representations were made to PBIO in a transaction in which PBIO had an interest. Auxocell supplied false information for the guidance of PBIO. Auxocell did not exercise

reasonable care or competence in obtaining or communicating the information. PBIO justifiably relied on Auxocell's representations.

76. As a proximate and foreseeable result of Auxocell's misrepresentations, PBIO has been damaged and incurred actual and special damages, for which damages PBIO hereby sues.

SEVENTH CLAIM FOR RELIEF
(Violations of Utah Truth in Advertising Act)

77. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

78. Utah's Truth in Advertising Act prohibits representations that goods "have…characteristics…uses, benefits, or qualities that they do not have," representations that goods "are of a particular standard, quality, or grade…if they are of another," and advertisement of goods "with intent not to sell them as advertised." Utah Code § 13-11a-3.

79. Auxocell violated the Truth in Advertising Act by claiming that its product would be suitable for use in a process that required sterile conditions and uncontaminated results. In actuality, the product was not suitable for that process, and resulting tissue samples contained visible amounts of metal particulates after being processed with the device.

80. Recoverable damages include the amount of actual damages, mandated attorneys' fees, and the costs of litigation. Utah Code § 13-11a-4(2).

EIGHTH CLAIM FOR RELIEF
(Violations of Utah Unfair Practices Act)

81. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

82. Utah's Unfair Practices Act makes it unlawful to "advertise goods, wares, or merchandise that a person is not prepared to supply." Utah Code § 13-5-8.

83. Auxocell violated the Unfair Practices Act by advertising and accepting PBIO's payment for equipment that would allegedly be suitable for use in a process that required sterile conditions and uncontaminated results. In actuality, the equipment was not suitable for that process, and resulting tissue samples contained visible amounts of metal particulates after being processed with the device. Thus, Auxocell was not prepared to and did not supply the product that it advertised.

84. Recoverable damages include "three times the amount of the actual damages sustained … plus court costs." Utah Code § 13-5-14.

NINTH CLAIM FOR RELIEF
(Unjust Enrichment/Quantum Meruit)

85. PBIO hereby incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein

86. To the extent that the Court may find that there was no agreement, Auxocell has been substantially enriched as a result of PBIO's payments to Auxocell.

87. At all relevant times, Auxocell was aware of, appreciated the nature of, and benefitted from PBIO's payments, while providing PBIO no corresponding value.

88. In light of Auxocell's knowing receipt of these substantial benefits, its receipt of PBIO's payments is wrongful and has caused injury to PBIO.

89. PBIO has been injured in an amount to be proven at trial.

JURY DEMAND

Plaintiffs request a jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, PBIO demands judgment against Auxocell:

A. For relief as prayed above;

B. To the extent permitted by applicable law, for an award of reasonable attorney fees, costs, pre- and post-judgment interest; and

C. For such other and further equitable and just relief, as the Court deems appropriate.

Dated: March 18, 2020

Respectfully submitted,

By: /s/ Brent O. Hatch
HATCH LAW GROUP, PC
Brent O. Hatch

Attorneys for Predictive Biotech, Inc.